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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,651	07/08/2002	Elisabeth Csoregi	50159-026	5727

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MCDERMOTT WILL & EMERY
600 13TH STREET, N.W.
WASHINGTON, DC 20005-3096

EXAMINER
GUO, LYNDA T

ART UNIT	PAPER NUMBER
1651	//

DATE MAILED: 02/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	10/019,651	CSOREGI ET AL.	
	Examiner	Art Unit	
	Lynda T Guo	1651	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 July 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the Application

The Substitute Declaration and Power of Attorney (Paper No. 10) received on 04 November 2002 has been entered.

Claims 1-12 of the instant Application are pending.

Priority

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Sweden on 06 July 1999.

2.

Information Disclosure Statement

3. The listing of references in the Search Report is not considered to be an information disclosure statement (IDS) complying with 37 CFR 1.98. 37 CFR 1.98(a)(2) requires a legible copy of: (1) each U.S. and foreign patent; (2) each publication or that portion which caused it to be listed; (3) for each cited pending U.S. application, the application specification including claims, and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion; and (4) all other information, or that portion which caused it to be listed. In addition, each IDS must include a list of all patents, publications, applications, or other information submitted for consideration by the Office (see 37 CFR 1.98(a)(1) and (b)), and MPEP § 609 subsection III. A(1) states, "the list ... must be submitted on a separate paper." Therefore, the references cited in the Search Report have not been considered. Applicant is advised that the date of submission of any item of information or

any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the IDS, including all "statement" requirements of 37 CFR 1.97(e). See MPEP § 609 subsection III. C(1).

Specification

4. The disclosure is objected to because of the following informalities: numerous typographical, grammatical and spelling errors found in the instant Specification (see below).

On page 3, line 17 and page 6, line 10, "di**metyl**bipyridine" is a misspelling;

On page 3, line 32, "fore" is a misspelling;

On page 3, line 38, a punctuation mark is missing at the end of the paragraph;

On page 4, line 32 and page 7, line 30, "PV_{13}-dmeOs" should be corrected to ---PVI_{13}-dmeOs---;

On page 5, lines 17-19, the sentence "Then the active form....see mechanism II." Is awkward and seems to repeat lines 5-8 of the same page'

On page 8, line 12, "an the top" should be changed to ---**on** the top---;

On page 12, line 23, the word "metyldiator" is queried;

On page 13, line 3, "0,5" should be corrected to ---0.5---;

On page 15, line 15, "**etylene**" is a misspelling.

Appropriate correction is required.

Claim Objections

5. Claims 5 and 6 are objected to because of the following informalities:

In Claim 5, "di**metyl-bipyridin**" and "**etylene**glycol" are incorrectly spelled.

In Claim 6, "direct" in line 3 should be changed to ---directly---.

Appropriate correction is required.

Claim Rejections - 35 USC § 101/112

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1, 6, 8, 10 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Regarding claims 1, 8, 10 and 11, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

10. Claim 6 recites the limitation "the osmium based redox polymer" in lines 4-6. There is insufficient antecedent basis for this limitation in the claim. It is suggested that "the" be changed to "an".

11. Regarding claim 12, the phrase "preferably" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

12. Claims 10-12 provide for the use of the biosensor, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

13. Claims 10-12 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example Ex parte Dunki, 153 USPQ 678 (Bd.App. 1967) and Clinical Products, Ltd. v. Brenner, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heller et al. (WO 199323748) in view of Ohashi et al. (USPN 5,565,329).

Claims 1-9 are directed to a biosensor comprising an electrode (preferably graphite, but can also be made of noble metals, other carbon-based material, conducting salts or conducting polymers) and either a mono-enzyme or bi-enzyme system of a copper-containing amine oxidase, derived from grass pea, and a peroxidase, from horseradish, soybean, tobacco, sweet potato or palm tree, preferably horseradish. Various embodiments of the biosensor include: 1) direct adsorption of the enzyme system to the electrode, or 2) cross-linking the enzyme system to a redox polymer. The enzyme system can be cross-linked to an osmium based redox polymer, poly(1-vinyl-imidazole) complexed to $[Os(4,4'\text{-dimethyl-bipyridine})_2Cl]^{+/2+}$, via the cross-linking agent, poly(ethylene-glycol)diglycidyl-ether (PEGDGE). Claim 10 is directed to the use of the biosensor for detecting biomarkers as an indicator of food freshness.

Heller et al. teaches the use of osmium-based redox polymers in enzyme electrodes. The electrodes may be of the mono-enzyme or bi-enzyme type. The enzymes may be immobilized either together in the redox polymer or in separate layers (see page 13, lines 25-27; page 14, lines 4-6; and page 15, line 12 through page 17, line 13). The electrode disclosed may be formed of various materials including gold, platinum, palladium, tin oxide, glassy carbon, graphite, or conducting organic salts (page 9, lines 10-16). The peroxidase used can be horseradish peroxidase (page 10, line 1) and the preferred redox polymer is osmium-based, including derivatives of poly(N-vinyl-imidazole) complexed with $[Os(bpy)_2Cl]^{+/2+}$ (page 11, lines 13-15 and 24-26). Cross-linking agents disclosed include PEGDGE (page 12, lines 15-17). Oxidases such as D-amino acid oxidase and glucose oxidase were exemplified in this disclosure (Page 26,

Example 4). Heller et al. does not teach the use of grass pea-derived, copper-containing amine oxidase or the use of the biosensor for determining freshness of food by detecting the biomarkers.

However, Ohashi et al. teaches that the amine histamine is found in foods such as fish and meat that are contaminated. An analyzer is also disclosed for the detection of histamine to determine freshness of food. (See Column 1, lines 15-23; Column 2, lines 43-61.) The analyzer disclosed by Ohashi et al. utilizes an enzymatic reagent having specifically strong oxidase activity to histamine. The enzyme used is a copper-containing amine oxidase (EC 1.4.3.6) extracted from Aspergillus niger (Column 3, lines 2-4, 24-40).

One of ordinary skill in the art would have been motivated to modify the biosensor as taught by Heller et al. by substituting the oxidase into a copper-containing amine oxidase (EC 1.4.3.6) because copper-containing amine oxidases (EC 1.4.3.6) are useful in determining freshness of foods to due the enzyme's strong reactivity to histamine. Although Claims 1 and 2 recites that the amine oxidase is derived from grass pea, one could have easily substituted this with an enzyme derived from Aspergillus niger or another organism because irrespective of the source, all enzymes in EC 1.4.3.6 (copper-containing amine oxidases) would have the same results because these enzymes have the same reaction mechanism.

Therefore, absent any unexpected results, the invention as a whole would have been prima facie obvious.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynda T Guo whose telephone number is (703) 605-1200. The examiner can normally be reached on Tue - Fri and alternate Mondays (9:00am - 7:00pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on (703) 308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Lynda T Guo
Patent Examiner
February 7, 2003

Jon P. Weber, Ph.D.
Primary Examiner